K072445

Nucletron

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	Integrated Brachytherapy Unit - Digital
Common/Usual Name:	Fluoroscopic / radiographic radiation treatment simulation system
Classification Name:	System, Simulation, Radiation Therapy
Classification:	21Cfr892.5840 Class II
Product Code	KPQ

Legally Marketed Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Integrated Brachytherapy Unit	K973848

Description:

Integrated Brachytherap Unit – Digital (IBU-D) is a modification to the Integrated Brachytherapy Unit (IBU) in which the Image Intensifier of the IBU is replaced by a Flat Panel image detector. The Flat Panel image detector used in the IBU-D is the same Flat Panel image detector as used in Nucletron's Simulix Evolution product (K03347)

The Integrated Brachytherpay Unit – Digital (IBU-D) is a localization and simulation device for a Brachy radiation therapy department. It consists of a gantry that supports an L-arm and a C-arm which can rotate isocentrically. The C-arm houses an X-ray tube housing assembly with collimator on one side and a flat panel image detector. The movements of the IBU-D are manually driven, after the relevant electrical locks are lifted. The mobile IBU patient table has mechanical motions which can be controlled from a hand pendant affixed to the table. Images are displayed and managed by a PC based workstation running specialized software.

The system makes also use of the same third party X-ray tube and X-ray high tension generator as used in the Simulix Evolution system.

The Flat Panel image detector which replaces the current Image Intensifier is a Amorphous silicon, digital detector, with a square image area of 41 x 41 cm.

The PC based workstation runs the same software as the workstation of the Simulix Evolution system. It supports the following functionality:

- Image acquisition
- Image display
- Image annotation
- Database and DICOM Import / Export functionality
- Position read out and display of the IBU-D gantry.
- Control of the IBU-D beam limiting device.

The last two items in this list are specific for the IBU-D.

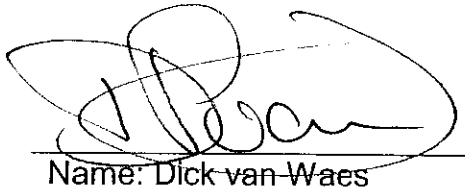
Intended use:

The modified device has the same intended use as the legally marketed predicate device cited:

The Integrated Brachytherapy - Digital (IBU-D) is intended to be used for the visualization, localization and confirmation of the volume and the size of the brachytherapy irradiation field(s), using a fluoroscopic and/or radiographic system.

Summary of technological considerations:

Integrated Brachytherapy Unit - Digital is substantially equivalent to the cleared predicate device, Integrated Brachytherapy Unit, 510(k)#: K973848.



Name: Dick van Waes
Title: Business Director Brachytherapy & Imaging
Nucletron B.V.
Veenendaal, The Netherlands

13 AUG 2007
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 14 2007

Ms. Lisa Dimmick
Director, Regulatory Affairs and Quality Assurance
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046

Re: K072445
Trade/Device Name: Integrated Brachytherapy Unit - Digital
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy stimulation system
Regulatory Class: II
Product Code: KPQ
Dated: August 13, 2007
Received: August 30, 2007

Dear Ms. Dimmick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number	K072445
Device Name	Integrated Brachytherapy Unit - Digital
Indications for Use	The Integrated Brachytherapy - Digital (IBU-D) is intended to be used for the visualization, localization and confirmation of the volume and the size of the brachytherapy irradiation field(s), using a fluoroscopic and/or radiographic system.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072445

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)